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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,771	ESCARGUEL, CLAUDE	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed January 15, 2009 has been entered. Claims 1-34 has been amended. Claim 13 is withdrawn from consideration. Claims 1-12 and 14-34 are under consideration in this office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The objection of claims 2-12 and 14-34 under 37 CFR 1.75(c);

b) The rejection of claims 1-12 and 14-34 under 35 U.S.C. 112, second paragraph regarding claims 1-2, 4-12 and 14-34, the phrases "preferably", "optionally", "when applicable" and "corresponding" in claims 1 and 18;

c) The rejection of claim 1, step (2) under 35 U.S.C. 112, second paragraph

d) The rejection of claims 4, 9, 15 and 31 under 35 U.S.C. 112, second paragraph for improperly expressed alternative limitations

e) The multiply dependant rejection of claim 7 under 35 U.S.C. 112, second paragraph; and

f) The dependency rejection of claim 14, under 35 U.S.C. 112, second paragraph

Response to Arguments

3. Applicant's arguments filed January 15, 2009 have been fully considered but they are not persuasive.

Objections

4. Dependant claims 2-12 and 14-23 and 25-34 refer to "A method as in claim 1" "A kit as in claim 24", however the suggested claim language is to use of the article "The." Therefore the suggested claim language is "The method as in claim of 1" or "The kit as in claim 24."

5. Claim 3 is objected to because of the following informalities: Claim 3 appears to be missing words "...in that it is controlled that said tested sample..." Therefore clarification is required to overcome the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 and 14-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In claim 1, step (d) it is unclear how the method controls the presence of a human serum in the tested sample. Therefore clarification is required to overcome the rejection.

Applicants assert that there are several known methods to control the presence of a human serum in a tested sample. However the claim is still unclear. It is unclear if the claim is testing or making a positive control or if the term "controlling" refers to the determination of a positive reaction. It is noted that 1(b) and (c) clearly recite controlling by reciting a verification step. Therefore clarification is required to overcome the rejection.

b) The preamble of the claims is drawn to *in vitro* serological method for diagnosing microbial agents by immunodetection. There is no correlation step which correlates the *in vitro* serological method for diagnosing microbial agents by immunodetection to the reaction of the first control antigen, the lack of reaction of the second control antigen and when applicable the reaction of the third control antigen with the first detection substance in the even of an IgM assay.

c) Applicants assert that Claim 1, Step 2 where a reaction between the microbial antigen and serum sample and the detection substance are taken into account is sufficient. However, at best, that step only detects the presence of the microbial agent under the recite set of conditions, it does not diagnosis microbial agents. Therefore, the goal of the preamble is not commensurate with the steps of the method, since no diagnosis of microbial agents seemed to be achieved.

d) Regarding claim 3, the phrases "preferably" render the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

e) Claim 3 is unclear. The claim recites "fourth control antigen is attached in the presence of said second detection substance which is a substance reacting with an immunoglobulin of the patient species and not reacting with said fourth control antigen, preferably an anti-immunoglobulin antibody of the patient species not reacting with said fourth control antigen, the control of the presence of a serum being positive if said fourth antigen reacts with said serum sample and said second detection substance." Therefore the attached 2nd detection substance does not react with the 4^{th} control antigen but the claim then states that the control of the presence of the serum being positive occurs if the 4^{th} antigen reacts with the serum and the 2^{nd} detection substance. Therefore the claim is unclear and inconsistent by stating that the 2nd detection substance and 4^{th} control do not react and then recite that the 4th and 2nd can react.

While it is noted that Applicants have attempted to address the issues by point to page 13, this does not overcome the rejection. In response to applicant's argument, it is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

f) Claims 11 and 20 recites alternative limitations which are improperly expressed. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4."

It is noted that claims 4, 9, 15 and 31 have been amended, however claims 11 and 20 are still rejected.

g) Claim 17, recites the limitation "said immunoglobulin specific to said vaccine agent to be detected" in the claim. Claim 1 does not recite an immunoglobulin specific to said vaccine agent. The examiner acknowledges Applicants' argument, however there is insufficient antecedent basis for this limitation in the claim.

h) The phrase "cut off value" in claim 21 is a relative phrase which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the cut-off value is unclear, since it is unclear what determines the cut-off value. It is unclear what the cutoff value is. While, the Office acknowledges the amendment, clarification is still required to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The rejection of claims 1-12 and 14-34 under 35 U.S.C. 102(b) as being anticipated by Wong et al., (US Patent 5,478,753 published December 26, 1995) is maintained for reasons of record.

The rejection is on the grounds that Wong et al., teach an *in vitro* serological assay method for diagnosing microbial agents by immunodetection, wherein the presence is detected and the quantity of patient immunoglobulins is assayed of both classes M and G, or only class G, specific to a microbial antigen characteristic of the microbial agent, in a patient's serum sample to be tested, by detection of an immunological reaction complex between said microbial antigen to be detected and a said specific, class M immunoglobulin for IgM assay and/or respectively a said specific, class G immunoglobulin for IgG assay using a first detection substance and/or respectively a second detection substance, comprising an antibody only reacting with a said immunoglobulin of the patient species of class M and/or respectively G. Wong et al., also teach a diagnosis kit and method of preparing a solid support on which at least one microbial antigen is attached.

Applicants argue that because the summary statement of the claims only recites the preamble, that Wong et al. do not teach the invention. However, the office action of October 15, 2008 recites with great detail all the teachings of Wong et al, and not just the recitations of the preamble as stated by Applicant. Wong et al., teach the serum sample and first and second detection substances, or only the second detection substance being contacted with at least one solid support on which the following antigens have been attached: a first control antigen consisting of a non-specific class G

immunoglobulin of the patient species, and a second control antigen containing DNA/histone complexes, and optionally a third control antigen [See Wong et al., teach there is immobilized to a solid carrier a capture material, a fluid (serum) sample and a labeled conjugate are brought into contact with the solid carrier material. Wong et al., teach IgG, IgA, IgD, IgM or IgE as control antigens.

Applicants' argue that the instant invention requires a third antigen control consisting in a non-specific class M immunoglobulin being bound to the solid support when IgM is tested. However Applicant is reminded that claim 1 recites "optionally, a third control antigen." Thus the third control antigen is not a required limitation of the claim. Therefore Applicants argument is not persuasive.

Alternatively, Wong et al., teach providing a third calibrator/control composition, nonspecific IgM immunoglobulin. This is a non-specific class M immunoglobulin of the patient species used in IgM serology assays. Wong et al., teach the third control reacting with a first detection substance, while teaching a variety of detection substances. Therefore applicants' argument is not persuasive.

Furthermore, Applicants assert that the instant invention comprises non-specific class M immunoglobulin to be bound to the support when IgM is tested. In response to applicant's argument that the Wong et al., reference fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., there is no requirement that non-specific class M immunoglobulin be bound to the solid support are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The third control antigen is optional, and only need in the event of IgM assay; thus the optional third control antigen is not need for other assays which the claim embraces. Therefore applicants' argument is not persuasive.

Applicants assert that Wong et al., teach the non-specific IgM covalently linked to a non IgM antibody which is not required for the instantly claimed third control antigen. Again, Applicant is reminded that the third control antigen is optional. However the claim language recites "comprises." The transitional term comprises is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Therefore applicants' argument that Wong et al., do not anticipate the in vitro serological assay method because it discloses an additional element to link the IgM is not persuasive since Wong et al., meets the limitations of the claims and the inclusion of additional elements is not prohibited by the claim.

Applicants' argue that Wong et al., does not teach non-specific class G immunoglobulin and a second control antigen containing DNA/histone complexes.

Contrary to applicants' statements, Wong et al., teach providing calibrator/control compositions for use including IgG antibodies since they are abundant and readily available. Wong et al., provide calibrator/control compositions for use in an assay to detect antibodies to infectious diseases, thus as long as the material can detect in the assay, then the teachings of Wong et al., embrace the material. Therefore because of the broad description by Wong et al., Wong inherently discloses the inclusion of DNA/histone complexes, contrary to applicants' assertion.

Finally, Wong et al., teach calibrator and control compositions for IgM serology assays testing for infectious diseases. Therefore Wong et al., teach the instantly claimed invention despite applicants' arguments. Therefore applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645